U.S. Department of Justice

United States Attorney
Southern District of New York

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April 23, 2015

BY ECF and FACSIMILE (212) 805-7986
Hon. Paul G. Gardephe
United States District Judge
United States Courthouse
40 Foley Square
New York, NY 10007

Re: *United States v. Novartis*, No. 11 Civ. 0071 (PGG)

Dear Judge Gardephe:

The parties in the above-referenced *qui tam* action write respectfully pursuant to Paragraph 7 of the Court's initial Case Management Plan and Scheduling Order of November 24, 2014, which directed the parties to provide an update regarding the current status of discovery and to present a detailed plan for the completion of discovery in advance of the pretrial conference scheduled for April 30, 2015, at 10:00 a.m.

Brief Description of the Case

This is an action under the False Claims Act (the "FCA"), 31 U.S.C. §§ 3729(a)(1)(A)-(B), in which the United States and the State of New York state have intervened claiming that Defendant Novartis Pharmaceuticals Corporation ("NPC") provided remuneration through speaker programs to physicians to induce them to prescribe NPC's cardiovascular drugs, and thereby caused false claims for reimbursement to be submitted to federal and state healthcare programs in violation of the FCA as well as the Anti-Kickback Statute (the "AKS"), 42 U.S.C. § 1320a-7b, and related New York State laws. Relator Oswald Bilotta originally commenced this action as a relator under the FCA on behalf of the United States, New York and several other states and municipalities.

NPC disputes the allegations underlying the plaintiffs' claims, and disputes that it is liable under the FCA, the AKS or any related state laws in connection with those claims.

Current Status of Discovery

Since the last pretrial conference held on October 27, 2014, the parties have been working diligently and collaboratively on discovery-related matters. Specifically, given the breadth of the allegations in this case – which, as pleaded in the Government's August 26, 2013, Amended Complaint span nine years, within which time tens of thousands of NPC speaker

programs concerning the drugs in issue were conducted – the parties have been working together to narrow the scope of discovery to something manageable and less burdensome. That process has been challenging and time-consuming, involving three lengthy meet and confer sessions, and the analysis, exchange and discussion of information regarding the historical data available at NPC and the burden associated with linking discovery to specific healthcare providers, events and/or NPC sales representatives.

The parties have made substantial progress as to several challenging issues, including, for example, a protocol for narrowing the list of potential record custodians from among the thousands of NPC sales representatives and the identification of the types of marketing and promotional activities for which NPC will provide discovery. It is the Government's view, however, that there are a number of substantive issues that remain to be resolved with respect to discovery going forward, including, for example, the protocol for conducting electronic searches of NPC's management personnel, following NPC's disclosure of a proposed protocol to the Government on April 3, 2015. The parties anticipate continuing to negotiate the details of a protocol that will be acceptable to both plaintiffs and defendant in the upcoming weeks.

Although the parties have been engaged in a collaborative process in an effort to resolve any disputes related to the scope of discovery without need for judicial intervention, there are several issues as to which the parties have not been able to reach agreement. The Government will therefore be submitting a separate pre-motion conference letter outlining those issues, so that the parties may obtain prompt resolution of these disputes. NPC will respond to that letter, once it is received.

Notwithstanding that ongoing meet and confer process, the United States and NPC have both commenced document productions:

(a) To date, the United States has produced approximately 94,494 pages of discovery material to NPC, and anticipates that it will produce an additional 14,000 pages within the next week. With that production, the United States will have substantially completed its responses to all but three of NPC's document requests. With respect to the remaining three requests, the United States has agreed to work with New York and various agencies throughout the country to collect data showing the claims submitted for reimbursement to federal and state health care programs for the subject drugs, and the United States will also collect claims data for an agreed upon list of comparator drugs. The United States and New York will commence this data collection as soon as the parties arrive at an agreement regarding the list of NDC codes to be used in this data collection.

(b) NPC produced over 2.5 million pages of documents during the investigation phase, and has now produced an additional 117,222 pages to plaintiffs, that were collected from custodians in NPC's headquarters. That document production will continue on a rolling basis.

Proposed Plan for the Completion of Discovery

Based on the progress of discovery to date, the parties believe that the schedule set forth in the joint proposed case management plan previously submitted to the Court on October 20, 2014, remains workable. Attached hereto as Exhibit A is the joint proposed case management plan that was previously submitted. As set forth in that proposal, the deadline for all fact discovery would be January 29, 2016, and the deadline for all expert discovery would be May 13, 2016.

The parties presently anticipate that they will be able to complete discovery within that timeframe, but note that there are some potential uncertainties which may impact the parties' ability to meet those deadlines. It is difficult at this point to predict precisely how long discovery will take because we have not yet resolved all of the details related to the discovery protocol for collecting and reviewing documents from NPC's sales force, which we expect to account for a large volume of materials. Depositions likely cannot commence until that is complete. Additionally, this case will likely involve depositions from numerous third parties, including health care professionals and former NPC employees, whose availability is not within the parties' control. Nonetheless, the parties intend to continue working diligently and will make every effort to meet those deadlines.

Counsel for all parties would be happy to address any aspect of this report and proposed plan at the upcoming conference scheduled for April 30, 2015.

Respectfully,

PREET BHARARA
United States Attorney

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